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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/550,453	08/18/2006	Gina Fischer	028232-0113	3166

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EXAMINER	
SASAN, ARADHANA	
ART UNIT	PAPER NUMBER
1615	
MAIL DATE	DELIVERY MODE
06/07/2011	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Advisory Action Before the Filing of an Appeal Brief	**Application No.** 10/550,453	**Applicant(s)** FISCHER ET AL.
	Examiner ARADHANA SASAN	**Art Unit** 1615

--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED 19 May 2011 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE.

1. ☒ The reply was filed after a final rejection, but prior to or on the same day as filing a Notice of Appeal. To avoid abandonment of this application, applicant must timely file one of the following replies: (1) an amendment, affidavit, or other evidence, which places the application in condition for allowance; (2) a Notice of Appeal (with appeal fee) in compliance with 37 CFR 41.31; or (3) a Request for Continued Examination (RCE) in compliance with 37 CFR 1.114. The reply must be filed within one of the following time periods:
   a) ☒ The period for reply expires *3* months from the mailing date of the final rejection.
   b) ☐ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection.

   Examiner Note: If box 1 is checked, check either box (a) or (b). ONLY CHECK BOX (b) WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

NOTICE OF APPEAL

2. ☐ The Notice of Appeal was filed on _____. A brief in compliance with 37 CFR 41.37 must be filed within two months of the date of filing the Notice of Appeal (37 CFR 41.37(a)), or any extension thereof (37 CFR 41.37(e)), to avoid dismissal of the appeal. Since a Notice of Appeal has been filed, any reply must be filed within the time period set forth in 37 CFR 41.37(a).

AMENDMENTS

3. ☒ The proposed amendment(s) filed after a final rejection, but prior to the date of filing a brief, will not be entered because
   (a) ☒ They raise new issues that would require further consideration and/or search (see NOTE below);
   (b) ☐ They raise the issue of new matter (see NOTE below);
   (c) ☐ They are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or
   (d) ☐ They present additional claims without canceling a corresponding number of finally rejected claims.

   NOTE: *The limitations of: "an erodible" matrix comprising "a polyethylene glycol, a polyethylene oxide and/or a block copolymer of ethylene oxide and propylene oxide"; a "single" coating; and the release profile parameters that were added in claim 64 were not previously presented and raise new issues which require further search and consideration.* . (See 37 CFR 1.116 and 41.33(a)).

4. ☐ The amendments are not in compliance with 37 CFR 1.121. See attached Notice of Non-Compliant Amendment (PTOL-324).
5. ☐ Applicant's reply has overcome the following rejection(s): _____.
6. ☐ Newly proposed or amended claim(s) _____ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).
7. ☐ For purposes of appeal, the proposed amendment(s): a) ☐ will not be entered, or b) ☐ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.
   The status of the claim(s) is (or will be) as follows:
   Claim(s) allowed: _____.
   Claim(s) objected to: _____.
   Claim(s) rejected: _____.
   Claim(s) withdrawn from consideration: _____.

AFFIDAVIT OR OTHER EVIDENCE

8. ☐ The affidavit or other evidence filed after a final action, but before or on the date of filing a Notice of Appeal will not be entered because applicant failed to provide a showing of good and sufficient reasons why the affidavit or other evidence is necessary and was not earlier presented. See 37 CFR 1.116(e).
9. ☐ The affidavit or other evidence filed after the date of filing a Notice of Appeal, but prior to the date of filing a brief, will not be entered because the affidavit or other evidence failed to overcome all rejections under appeal and/or appellant fails to provide a showing a good and sufficient reasons why it is necessary and was not earlier presented. See 37 CFR 41.33(d)(1).
10. ☐ The affidavit or other evidence is entered. An explanation of the status of the claims after entry is below or attached.

REQUEST FOR RECONSIDERATION/OTHER

11. ☒ The request for reconsideration has been considered but does NOT place the application in condition for allowance because: See Continuation Sheet.
12. ☐ Note the attached Information *Disclosure Statement*(s). (PTO/SB/08) Paper No(s). _____
13. ☐ Other: _____.

/Aradhana Sasan/ Examiner, Art Unit 1615	/Robert A. Wax/ Supervisory Patent Examiner, Art Unit 1615

Continuation of 11. does NOT place the application in condition for allowance because:
Applicant's arguments regarding the rejection under 35 USC 103(a) over Rao et al. (US 2003/0203055 A1) have been fully considered but are not persuasive. Applicant argues that the skilled artisan would not have had any reasonable expectation that selecting and combining isolated aspects of the different compositions of Examples 6 and 10 would result in a composition that achieves controlled delivery. This is not persuasive because the structure (components and arrangement) of the composition, the sustained release from the composition, and the method for treating visceral pain are all taught by Rao. The sustained release dosage form can include the active ingredient and a polyethylene oxide carrier, which is coated with a wall comprising ethylcellulose (Page 19, [0273]). The sustained release dosage form can also include the active ingredient and a polyethylene oxide carrier, which is coated with an interior wall comprising ethyl cellulose and an exterior wall containing cellulose acetate (Page 19, [0274]). Moreover, Rao suggests more than one opening, because of the disclosure that the coating of the tablet can have “a plurality of formed apertures” exposing the core (emphasis added, Page 20, [0285]). MPEP 2141 states that it is obvious to combine prior art elements according to known methods to yield predictable results.

Applicant's arguments regarding the rejection under 35 USC 103(a) over Wong et al. (US 4,824,675) in view of Rao et al. (US 2003/0203055 A1) have been fully considered but are not persuasive. Applicant argues that the "tiny pills" of Wong consist of an active agent core surrounded by a wall and that Wong does not teach a matrix composition comprising a mixture as recited in instant claims. This is not persuasive because both Wong and Rao teach the delivery of an analgesic from a sustained release delivery device that contains an inner matrix comprising a polymer and the active, a wall surrounding the matrix formed of impermeable materials, and having an opening or exit in the wall. One of ordinary skill in the art knows that analgesics are used in the method of treating pain and that opioids are used for treating pain, as evidenced by Rao. It is obvious to substitute one known element (analgesics for pain – taught by Wong) for another (opioid for pain – taught by Rao) and obtain predictable results. Please see MPEP 2141.

Applicant's arguments regarding the rejection under 35 USC 103(a) over DePrince et al. (US 4,898,733) in view of Rao et al. (US 2003/0203055 A1) have been fully considered but are not persuasive since they are drawn to the limitations in claim amendments ("single coating") which have not been entered. Both DePrince and Rao teach the delivery of an analgesic from a sustained release delivery device that contains an inner matrix comprising a polymer and the active, a wall surrounding the matrix formed of impermeable materials, and having an opening or exit in the wall.

Applicant's arguments regarding the rejection under 35 USC 103(a) over Rao et al. (US 2003/0203055 A1) in view of Sackler et al. (US 5,478,577) have been fully considered but are not persuasive. Applicant argues that the skilled artisan would not have had a reason to select and combine isolated components of the compositions of Sackler and Rao since they operate on different principles, and would not have had any reasonable expectation of achieving a controlled release composition that exhibits the delivery and dissolution profiles recited in instant claims. Sackler teaches the once daily dosing of the opioid and is properly combined with Rao because both references are drawn to methods for providing effective pain management in humans and the combination of prior art elements according to known methods is obvious.